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10/566,873	07/03/2006	Rachel Butler	T3140(C)	9573

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EXAMINER

NEGRELLI, KARA B

ART UNIT	PAPER NUMBER
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1796

NOTIFICATION DATE	DELIVERY MODE
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12/18/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/566,873	Applicant(s) BUTLER ET AL.	
	Examiner KARA NEGRELLI	Art Unit 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/30/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

POROUS MATERIAL AND METHOD OF PRODUCTION THEREOF

DETAILED ACTION

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any rejections stated in the previous Office Action and not repeated below are withdrawn.
3. The instant office action contains new positions using prior art which was applied in rejections previously presented. Therefore, this action is properly made NON-FINAL.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-21 and 23-30 rejected under 35 U.S.C. 103(a) as being unpatentable over Ko et al. (US 2003/0134918) and further in view of Butler et al. (Advanced Materials, "Emulsion Templating Using High Internal Phase Supercritical Fluid Emulsions."
6. Ko et al. teach compositions comprising replacing the oil in an oil-in-water emulsion with supercritical fluids, such as CO₂, that are non-toxic, environmentally friendly, more soluble, and cost effective (paragraph [0007]). After polymerization, the

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CO₂ is easily extracted from the polymer as a gas (paragraph [0008]). The supercritical CO₂ causes swelling of the polymeric matrix, allowing diffusion of surface active agents or other active components into the matrix in the swollen state, wherein upon depressurization, the matrix deswells and entraps the active components to modify properties of the foam (paragraph [0008]). By controlling the nature of the emulsion, and the polymerization process, nanopores can be created (paragraph [0008]). Ko et al. further teach that by depressurization, the CO₂ is vented away, and all or a portion of the oil phase is removed (paragraph [0044]).

7. Solvents, particularly those used in the liquid form, can be removed by freeze-drying (meaning the aqueous phase would at this point be at least partially frozen) (paragraph [0032]). Ko et al. do not expressly teach reducing the temperature of the emulsion to a range of from -5°C to -30°C. However, since Ko et al. teach freeze-drying the composition to remove solvent in a process which involves first freezing the substance and then subliming it (paragraph [0032]), one of ordinary skill in the art would recognize that freezing includes exposing the substance to temperatures which fall within instantly the claimed range.

8. Operations such as vacuum removal, removal driven by air pressure, pressing the foam, or other methods can be used to remove the oil phase, the supercritical fluid, remaining water, emulsifier, initiators, or any other unpolymerized material from the foam (i.e. there would be no solvent residue remaining in the material) (paragraph [0044]).

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9. Ko et al. further teach the use of surfactants such as polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monopalmitate (Tween 40) (paragraph [0021]). Further additives can also be used in the composition, such as solid metal nanoparticles (pertaining to instant claims 2-6 and 19-20), such as hydrophilic titanium oxide, silica, and the like (paragraph [0048]), as well as copper hydroxide or zinc hydroxide (organic reagents) as antimicrobial and/or odor control agents (paragraph [0065]).

10. Examples of the monomers to be polymerized for the composition of Ko et al. include polycarboxylic acid such as acrylic acid, vinyl lactams, aromatic vinyl sulfonic acids, carboxylic acid salt-containing monomers, N-hydroxyalkyl acrylamides (polyacrylamides, which the instant application recognizes is a water soluble matrix building material), methacrylic sulfonic acids, or acrylic sulfonic acids, (paragraph [0053]). The monomers are to be dispersed within the water phase of the invention (paragraph [0053]). The composition of may further comprise cellulosic fibers (paragraph [0049]). Because Ko et al. teach that these water soluble polymers may be dispersed in the aqueous phase of the emulsion, and because Ko et al. teach that carbon dioxide may completely substituted for the oil phase in a water-in-oil HIPE emulsion, and because crosslinking agents *may* be added to the composition (making them optional), the compositions of Ko et al. may be water-soluble porous materials. Ko et al. also teach that the porous materials may be molded into any desired shape (paragraph [0068]) (which would include a monolithic block, as described in claims 17 and 25).

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11. As to instant claims 17-18, case law holds that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). It is the examiner's position that the porous products of Ko et al. are capable of being formed into "any desired shape," and are not structurally different than the instant invention. "Any desired shape" would include a monolithic block or particles or beads.

12. Ko et al. further teach that the polymeric foam is used to produce absorbent articles (paragraph [0063]), including bandages or wound dressings (wound healing matrices) (paragraph [0010]).

13. The foams produced according to the invention of Ko et al. have pore volumes of from 6 cc/g to 200 cc/g. The bulk density would therefore be 1/200 g/cc to 1/6 g/cc, or from 0.005 to 0.16 g/cc (paragraph [0028]). The polymeric foam further has an average cell size of 50 microns or less (paragraph [0038]). These ranges overlap the values given in instant claim 23.

14. It is well settled that where the prior art describes the components of a claimed compound or compositions in concentrations within or overlapping the claimed concentrations a prima facie case of obviousness is established. See *In re Harris*, 409 F.3d 1339, 1343, 74 USPQ2d 1951, 1953 (Fed. Cir 2005); *In re Peterson*, 315 F.3d 1325, 1329, 65 USPQ 2d 1379, 1382 (Fed. Cir. 1997); *In re Woodruff*, 919 F.2d 1575,

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1578 16 USPQ2d 1934, 1936-37 (CCPA 1990); *In re Malagari*, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974).

15. It is noted that while 24-25 claim a water soluble porous material, all elected claims are recited in the product-by-process format by use of the language, "A water soluble porous material being produced in the form of..." Case law holds that:

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

16. To the extent that the process limitations in a product-by-process claim do not carry weight absent a showing of criticality, the reference discloses the claimed product in the sense that the prior art product structure is seen to be no different from that indicated by the claims.

17. Ko et al. do not expressly teach that the porous material of the invention is substantially free of cross-linking. However, Ko et al. teach that crosslinking materials are optional components (paragraph [0038]).

18. Ko et al. also do not expressly teach that method for producing the porous materials comprises from 5-20% w/v of matrix building material, from 5-20% w/v surfactant in respect of water, and 65-95% CO₂.

19. However, Butler et al. (2001) (*Advanced Materials* 2001, 13, 1459-1463) teaches CO₂-in-water emulsions comprising 70% to 80% CO₂, 10% w/v poly (vinyl alcohol) relative to water, and 1 to 10% surfactant w/v based on water (page 1460, column 2, paragraph 2, lines 1-4 and page 1461, paragraph 2, lines 5-8). It would have been obvious for one of ordinary skill in the art to use the concentrations of each component

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as specified by Butler et al. (*Advanced Materials* 2001, 13, 1459-1463) in the invention of Ko et al. because using the concentrations results in a system in which free-radical polymerization occurs before the emulsion becomes destabilized (Butler et al., *Advanced Materials* 2001, 13, page 1460, column 2, paragraph 2, lines 9-12). Addition of polyvinyl alcohol further counteracts destabilization when added to the aqueous phase of the emulsion before polymerization, resulting in an emulsion sufficiently stable for producing open-cell porous materials (Butler et al., *Advanced Materials* 2001, 13, page 1461, column 1, paragraph 2, lines 5-12). While Butler et al. teach that crosslinked acrylamide based polymers may be used to produce the porous materials, Butler et al. further teach that the invention may be applied to a much wider range of materials (page 1460, paragraph 3), and in an example, the crosslinked acrylamide is replaced with 2-hydroxyethyl acrylate, a water soluble matrix material. The substitution of acrylamide with 2-hydroxyethyl acrylate led to porous, open-cell materials suggesting that the technique described by Butler may be applied to a wide range of hydrophilic and hydrogel materials.

20. Both Butler et al. and Ko et al. are from the same field of endeavor: porous materials such as foams produce using CO₂ –in- water- emulsions. (See paragraph [00008] in Ko et al. and the first full paragraph of Butler et al., *Advanced Materials* 2001, 13, page 1460). It would have been obvious for one of ordinary skill in the art to use the materials of Butler et al. in the method of Ko et al. because the materials of Butler et al. lend to defined porous structures without the use of any volatile organic solvents. Additionally, paragraph [0009] of Ko et al. teaches that the Emulsion Templating Using

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Supercritical Fluid Emulsions” article by Butler et al. is incorporated by reference, as the technologies of Butler et al. can be adapted to improved HIPE polymerization processes used in the production of foams for absorbent articles, particularly using supercritical carbon dioxide to replace the oil phase in the HIPE foam-production processes to produce foams having higher capillary tension or other improved physical and interfacial properties relative to past HIPE foams.

Response to Arguments

21. As to the anticipation rejection over Ko et al. (US 2003/0134918), applicants' arguments are persuasive. However, on reconsideration, it has been determined that the prior art still qualifies under 35 USC 103(a).

22. The examiner notes that to qualify as prior art under 35 U.S.C 102 (b), the foreign priority date is not the effective filing date of the application. The effective filing date for the instant application is derived from the PCT of which the application is a national stage entry. The PCT application, PCT/GB04/03264 has an effective filing date of 07/29/2004, and therefore this date is the effective filing date of the instant application (regarding the applicants' argument on page 8, last paragraph of the arguments filed November 16, 2009). In any case, the rejection over Ko et al. under 35 U.S.C. 102 (b) has been withdrawn, and an explanation of why the art applies under 35 U.S.C 103 (a) is described below.

23. Applicant argues that Ko does not disclose the step of partially freezing the aqueous phase in the method of instant claim 1 and that Ko et al. also does not teach

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that an intermediate porous material is freeze-dried to at least partially remove the aqueous phase.

24. Applicants' argument is not persuasive. As applicant admits in paragraph 2 on page 9 of the arguments filed November 16, 2009, Ko et al. teach freeze-drying embodiments in which the solvent used freezes and then undergoes sublimation, passing from a frozen state to a solid state and then vaporizing (venting) from the composition. Because carbon dioxide is used as a solvent, if carbon dioxide is exposed to temperatures at which it passes from a liquid to a solid (in paragraph [0034] of Ko et al. carbon dioxide is described as a solvent), any water present (aqueous phase) would also be at least partially frozen.

25. Applicant further argues that in the methods disclosed by Ko et al., the resulting foams are not water-soluble. Applicant points to paragraph [0015] of Ko et al., asserting that Ko et al. states that a flexible foam is produced. Applicants further submit that the materials according to the present invention are not flexible and are quite brittle and easily crushed because of the porosity and absence of cross-linking. Applicant further argues that paragraph [0022] describes the cross-linkers used and specifically to the use of unsaturated carboxylic acid which may undergo cross-linking to form a superabsorbent polymer. Applicant further argues that paragraph [0038] of Ko refers to the use of a rubbery co-monomer and crosslinking agent.

26. Applicant argument is not persuasive. Paragraph [0015] of Ko et al. explicitly teaches that the foam structures of the present invention can be either flexible or rigid. Ko et al. teaches that a rigid foam ruptures (is easily crushed) when wrapped around a

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2.5 cm madrel at a uniform rate of 1 lap/5 seconds at 20°C. In addition, paragraph [0022] of Ko et al. teaches, very generally, crosslinking agents which **may** be added to the oil-in-water type emulsions, not that the components must be added to the composition taught by Ko et al. . Paragraph [0038] used the same language, stating that the compositions **may** additionally comprise rubbery co-monomers or crosslinkers. Because these components are optional, and because Ko et al. teach that the foams produced may be rigid and rupture when wrapped around a mandrel, the claims are obvious over Ko et al. in view of Butler et al. (Advanced Materials).

27. Applicant asserts that because the foams of Ko et al. absorb moisture they do not dissolve. Applicant argues that paragraph [0010] of Ko et al. refers to use of the polymeric foams in personal care items such as diapers and feminine hygiene products again showing that the polymeric foams absorb and do not dissolve. Applicant argues that paragraph [0018] refers to the use of monomers that produce a water-absorptive polymer.

28. Applicants argument is not persuasive. Examples of the monomers to be polymerized for the composition of Ko et al. include polycarboxylic acid such as acrylic acid, vinyl lactams, aromatic vinyl sulfonic acids, carboxylic acid salt-containing monomers, N-hydroxyalkyl acrylamides methacrylic sulfonic acids, or acrylic sulfonic acids, (which the instant application recognizes are water soluble matrix building materials) (paragraph [0053]). The monomers are to be dispersed within the water phase of the invention (paragraph [0053]). Because Ko et al. teach that these water soluble polymers may be dispersed in the aqueous phase of the emulsion, and because

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Ko et al. teach that carbon dioxide may be substituted completely for the oil phase in a water-in-oil HIPE emulsion, and because crosslinking agents *may* be added to the composition (making them optional), the compositions of Ko et al. may be water-soluble porous materials. Diapers and feminine hygiene products produced from the products of Ko et al. are but two examples of future intended uses for the materials disclosed by Ko et al. The fact that the foamed polymeric materials can be used in diapers and feminine hygiene products does not negate a finding of obviousness under 35 USC 103 since a preferred embodiment such as an example is not controlling. Rather, all disclosures "including unpreferred embodiments" must be considered. *In re Lamberti* 192 USPQ 278, 280 (CCPA 1976) citing *In re Mills* 176 USPQ 196 (CCPA 1972). Therefore, it would have been obvious to one of ordinary skill in the art to utilize a water soluble polymers may be dispersed in the aqueous phase of the emulsion, carbon dioxide completely substituted for the oil phase in a water-in-oil HIPE emulsion, without further use of crosslinking agents (because they are optional), making the compositions of Ko et al. may be water-soluble porous materials. In addition, feminine hygiene products and diapers are examples of future intended uses for the foams of Ko et al. Case law holds that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

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29. Additionally, Ko et al. incorporates the teachings of Butler et al. (Advanced Materials) therein by reference. Butler et al. teach that 2-hydroxyethyl acrylate polymers (page 1461, paragraph 3, last line) may be used to produce porous materials of a defined porosity, including microcellular foams. Therefore, it would have been obvious to one of ordinary skill in the art to utilize the porous, water soluble materials of Butler et al. in the method of Ko et al., meaning all the instant claim limitations are met.

30. Applicant argues that the production of a substantially water-soluble porous material without the use of chemical initiators or monomers is advantageous in use and the freeze-drying step allows isolation of a solid porous material that retains its structure, said advantages of which are not appreciated from the teach of Ko.

Applicants argument is not persuasive. It is noted that the features upon which applicant relies (i.e., production of a substantially water-soluble porous material without the use of chemical initiators or monomers and a freeze-drying step which allows isolation of a solid porous material that retains its structure) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

31. Even if these elements were in the claims, the freeze-drying step is disclosed by Ko et al., and the production of a water-soluble material without the use of chemical initiators or monomers is disclosed and/or suggested by Butler et al., page 1461, paragraphs 2-3. Butler teaches that the presence of organic monomers had caused significant destabilization which could be counteracted by the addition of polyvinyl

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acetate to the aqueous phase prior to polymerization. Butler teaches that the materials conformed to the interior of the reactions vessel (retained their structure). Butler et al. teach that the polymer C/W emulsion to which PVA may be added may comprise 2-hydroxyethyl acrylate (which the instant application recognizes as a water-soluble polymeric material in instant claim 10 and paragraph [0019] of the instant specification). A water-soluble surfactant is further added to the PVA and 2-hydroxyethyl acrylate C/W emulsion, resulting in a porous, polymeric material which is water soluble. See Example 4 of Butler et al. Butler et al. also teaches on page 1462, second paragraph, that the addition of PVA (polyvinyl alcohol) enhances the long-term stability of C/W emulsions in the absence of organic monomers such as acrylamide. The combination of Butler et al. and Ko et al. teaches the limitations of: the production of a substantially water-soluble porous material without the use of chemical initiators or monomers and a freeze-drying step which allows isolation of a solid porous material that retains its structure.

32. The argument that Butler et al. fails to teach the missing elements from Ko et al. and that Butler et al. teaches crosslinked polymers and teaches away from the instant invention is not persuasive for the reasons provided above. Ko et al. teach the freeze-drying method, and also that the Butler et al. reference is therein incorporated by reference. Therefore, it would have been obvious for one of ordinary skill in the art to use the materials of Butler et al. in the method of Ko et al. and to arrive at the instantly claimed invention.

33. The arguments with regards to claim 18 under 35 U.S.C. 103 (a) over Ko et al. in view of Rehmer are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA NEGRELLI whose telephone number is (571)270-7338. The examiner can normally be reached on Monday through Friday 9:30 am EST to 6:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571)272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARA NEGRELLI/
Examiner, Art Unit 1796

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